ART 34 AMDT

CLAIMS

1. A method for preparing a sterile pharmaceutical composition of a steroid comprising:-
(i) dissolving a non-sterile steroid in a solvent to yield a solution of the steroid,
(ii) filtering the solution to yield a sterile solution,
(iii) combining the sterile solution with sterile water to form a suspension,
(iv) optionally removing all or part of the solvent,
(v) treating the suspension to obtain a particle size distribution having a mass median diameter less than 10μm,
(vi) under sterile conditions combining the suspension with a pharmaceutically acceptable carrier to yield a sterile pharmaceutical composition comprising a suspension of the steroid having a mass median diameter less than 10μm, and
(vii) storing the sterile pharmaceutical composition in sterile containers.

2. A method according to Claim 1 wherein the non-sterile steroid is a powder.

3. A method according to Claim 2 wherein the powder is a micronized powder.

4. A method according to any of Claims 1 to 3 wherein the steroid is budesonide or fluticasone.

5. A method according to any of Claims 1 to 4 wherein the solvent comprises an alcohol.

6. A method according to any of Claims 1 to 4 wherein the solvent comprises a Class 3 solvent.

7. A method according to any of Claims 1 to 4 wherein the solvent comprises a Class 2 solvent.

8. A method according to any of Claims 1 to 7, comprising combining solvent with the steroid at a temperature from 20°C below the boiling point of the solvent up to its boiling point.

9. A method according to Claim 8 wherein the solvent is at reflux.

10. A method according to any of Claims 1 to 7 wherein the solvent is at 30-50°C.

11. A method according to any of Claims 1 to 10, comprising removing solvent under reduced pressure.

12. A method according to any of Claims 1 to 10 comprising removing solvent at atmospheric pressure.

13. A method according to any of Claims 1-12 using a filter having a pore size of 0.2µm or less.

14. A method according to any of Claims 1 to 13, wherein the water contains surfactant.

15. A method according to any previous Claim, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5µm.

16. A method according to Claim 15, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3µm.

17. A method according to any previous Claim, comprising storing the sterile composition in sterile ampoules.

18. Apparatus for preparing a sterile pharmaceutical composition of a steroid according to the method of Claim 1, comprising a container defining a sterile inner compartment, a sterile filter, a first vessel for containing a solvent, and a second vessel for containing a non-sterile steroid, arranged so that the solvent can be combined with the steroid to yield a solution, and the solution then filtered to yield a sterile solution within the compartment, the compartment also containing a sterile aqueous solution into which the sterile solution can be introduced to form a sterile suspension, optionally an apparatus for alteration of the particle size distribution of the suspension and further optionally a sterile exit line for transfer of sterile suspension to sterile containers.

19. Apparatus according to Claim 18, wherein the sterile filter has a pore size of 0.2µm or less.